



**COPY**

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450 Alexandria, VA 22313-1450 on 18 November 2004.

Signed: Paula Faulk Hurley  
Paula Faulk Hurley

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of: Niel F. Starksen  Application No.: 10/656,797  Filed: September 4, 2003  Title: Devices and Methods for Cardiac Annulus Stabilization and Treatment	Attorney Docket No.: GDS 1013-1 (formerly 016886-001300)  Examiner: Unassigned  Group: 3732  Customer Number: 22470
---	--

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**PRELIMINARY AMENDMENT**

Sir:

Before the first action in this case, please amend this application as follows.

**Amendments to the Claims** are reflected in the listing of claims, which begins on page 2 of this paper. This listing of the claims will replace all prior versions, and listings, of the claims in this application.

**REMARKS** begin on page 10 of this paper.

## **Amendments to the Claims**

Please **amend** claim 30 and **add** claims 58, 59 and 60 as follows. This listing of the claims will replace all prior versions, and listings, of the claims in this application.

1. (original) A method for stabilizing a valve annulus of a heart for performing a procedure on the valve annulus, the method comprising:

introducing at least a first stabilizing member beneath one or more leaflets of a valve of the heart to engage the annulus at an intersection between at least one leaflet and an interior ventricular wall of the heart; and

applying force to the first stabilizing member to stabilize the valve annulus.

2. (original) A method as in claim 1, wherein introducing comprises passing the member beneath at least the posterior leaflet of the mitral valve of the heart.

3. (original) A method as in claim 1, wherein applying force to the first stabilizing member exposes the valve annulus from surrounding tissue of the heart.

4. (original) A method as in claim 1, wherein introducing comprises advancing an elongate catheter carrying the first stabilizing member through vasculature of a patient to the heart, wherein the first stabilizing member is adapted to change between a flexible configuration for introduction through the vasculature and a curved configuration to conform to the annulus.

5. (original) A method as in claim 4, further comprising changing the shape of the first stabilizing member to conform to the annulus.

6. (original) A method as in claim 5, wherein changing the shape of the first stabilizing member comprises articulating the stabilizing member in at least two directions.

7. (original) A method as in claim 5, wherein changing the shape of the first stabilizing member comprises applying tension to at least a first tensioning cord to cause a first bend in the stabilizing member.

8. (original) A method as in claim 7, wherein changing the shape further comprises applying tension to at least a second tensioning cord to cause a second bend in the stabilizing member.

9. (original) A method as in claim 8, wherein the first bend comprises approximately a C-shaped bend to conform the stabilizing member to the annulus, and the second bend comprises an upwardly directed bend.

10. (original) A method as in claim 5, wherein changing the shape of the first stabilizing member comprises introducing a fluid into a shape-memory stabilizing member.

11. (original) A method as in claim 5, further comprising locking the shape of the first stabilizing member.

12. (original) A method as in claim 1, wherein applying force to the first stabilizing member comprises applying upwardly directed force in a direction from the ventricles toward the atria of the heart.

13. (original) A method as in claim 1, wherein stabilizing further comprises introducing at least a second stabilizing member over the valve leaflets.

14. (original) A method as in claim 13, further comprising moving the second stabilizing member toward the first stabilizing member to further stabilize the valve annulus.

15. (original) A method for stabilizing a valve annulus of a heart for performing a procedure on the valve annulus, the method comprising:

advancing a flexible, elongate stabilizing catheter through vasculature of a patient to the heart;

introducing at least a first stabilizing member of the stabilizing catheter beneath one or more leaflets of a valve of the heart to engage the annulus at an intersection between at least one leaflet and an interior ventricular wall of the heart;

changing the shape of the stabilizing member to conform to the annulus; and applying force to the stabilizing member to stabilize the valve annulus.

16. (original) A method as in claim 15, wherein changing the shape of the first stabilizing member comprises articulating the stabilizing member in at least two directions.

17. (original) A method as in claim 15, wherein changing the shape of the first stabilizing member comprises applying tension to at least a first tensioning cord to cause a first bend in the stabilizing member.

18. (original) A method as in claim 17, wherein changing the shape further comprises applying tension to at least a second tensioning cord to cause a second bend in the stabilizing member.

19. (original) A method as in claim 18, wherein the first bend comprises approximately a C-shaped bend to conform the stabilizing member to the annulus, and the second bend comprises an upwardly directed bend.

20. (original) A method as in claim 15, wherein changing the shape of the first stabilizing member comprises introducing a fluid into a shape-memory stabilizing member.

21. (original) A method as in claim 15, further comprising locking the shape of the first stabilizing member.

22. (original) A method as in claim 15, wherein applying force to the first stabilizing member comprises applying upwardly directed force in a direction from the ventricles toward the atria of the heart.

23. (original) A method as in claim 15, wherein stabilizing further comprises introducing at least a second stabilizing member over the valve leaflets.

24. (original) A method as in claim 23, further comprising moving the second stabilizing member toward the first stabilizing member to further stabilize the valve annulus.

25. (original) A method for constricting a valve annulus in a beating heart, the method comprising:

introducing at least a first stabilizing member beneath one or more leaflets of a valve of the heart to engage the annulus at an intersection between at least one leaflet and an interior ventricular wall of the heart of the heart;

applying force to the first stabilizing member to stabilize the valve annulus; and

constricting at least a portion of the valve annulus while the valve annulus remains stabilized.

26. (original) A method as in claim 25, further comprising:

introducing at least a second stabilizing member over the valve leaflets; and

moving the second stabilizing member toward the first stabilizing member further stabilize the annulus.

27. (original) A method as in claim 26, wherein constricting comprises attaching a mechanical support structure to at least a portion of the valve annulus.

28. (original) A method as in claim 27, wherein the mechanical support structure comprises a ring or a system of anchors and tethers.

29. (original) A method as in claim 26, wherein constricting comprises applying energy to shrink at least a portion of the annular tissue.

30. (currently amended) A method for constricting a valve annulus in a beating heart, the method comprising:

introducing at least a first stabilizing member beneath one or more leaflets of a valve of the heart to engage the annulus at an intersection between at least one leaflet and an interior ventricular wall of the heart of the heart;

applying force to the first stabilizing member to stabilize the valve annulus;

securing individual anchors at circumferentially spaced-apart locations about at least a portion of the valve annulus while the valve annulus remains stabilized; and

cinching a tether through the anchors to circumferentially tighten constrict the annulus.

31. (original) A method as in claim 30, further comprising:

introducing at least a second stabilizing member over the valve leaflets; and

moving the second stabilizing ring toward the first stabilizing ring to further stabilize the annulus.

32. (original) A method as in claim 31, wherein securing the anchors comprises driving the anchors from one of the first and second stabilizing members.

33. (original) A method as in claim 32, wherein driving the anchors from one of the first and second members comprises inflating an expandable balloon in one of the members to force the anchors at least partially out of the member into tissue of the valve annulus.

34. (original) A method as in claim 32, wherein securing the anchors further comprises driving the anchors through tissue of the valve annulus into an anchor receiving piece coupled with the other of the first and second stabilizing members.

35. (original) A device for accessing a valve annulus of a heart, the device comprising:

an elongate body having a proximal end and a distal end; and

a first stabilizing member at the distal end of the body, wherein the first stabilizing member is positionable under one or more leaflets of a valve of the heart to engage a length of the annulus along an intersection between at least one leaflet and an interior ventricular wall of the heart.

36. (original) A device as in claim 35, wherein the elongate body comprises a rigid shaft.

37. (original) A device as in claim 35, wherein the elongate body comprises a flexible catheter, so that the first stabilizing member may be positioned in the heart and under the one or more leaflets via a transvascular approach.

38. (original) A device as in claim 37, wherein the first stabilizing member comprises a shape-changing portion.

39. (original) A device as in claim 38, further comprising at least a first tensioning cord coupled with the shape-changing portion for applying tension to the shape-changing portion to cause it to bend in at least a first direction.

40. (original) A device as in claim 39, further comprising at least a second tensioning cord coupled with the shape-changing portion for applying tension to the shape-changing portion to cause it to bend in at least a second direction.

41. (original) A device as in claim 40, wherein the first direction comprises approximately a C-shape for conforming to the annulus and the second direction comprises an upward or proximal direction for applying force to the annulus.

42. (original) A device as in claim 39, wherein the shape-changing portion includes multiple notches along at least one side to control bending into a curve which conforms to the shape of the annulus.

43. (original) A device as in claim 39, wherein the shape-changing portion comprises multiple stacked segments coupled with at least the first tensioning member to control bending into the shape of the annulus.

44. (original) A device as in claim 38, wherein the shape-changing portion comprises a shape-memory material configured to conform to the shape of the annulus.

45. (original) A device as in claim 44, wherein the shape-changing portion further comprises at least one lumen for introducing a fluid to cause the shape-memory material to conform to the shape of the annulus.

46. (original) A device as in claim 35, wherein the first stabilizing member comprises:

- a semicircular housing;
- a plurality of tethered anchors disposed within the housing; and
- at least one expandable balloon for driving the plurality of anchors into tissue of the valve annulus.

47. (original) A device as in claim 46, wherein the anchors are selected from the group consisting of curved hooks, straight barbed hooks, clips, T-shaped fasteners, helical fasteners, rings, and shape memory fasteners.

48. (original) A device as in claim 46, further comprising at least one mandrel for releasably coupling the anchors with the housing.

49. (original) A device as in claim 48, wherein the anchors comprise a plurality of curved hooks, and wherein the mandrel comprises a pivot mandrel around which the hooks pivot to engage annular tissue.

50. (original) A device as in claim 46, further comprising:  
an inflation actuator for inflating the expandable balloon;  
a release actuator for releasing the anchors from the housing; and  
a cinching actuator for cinching a tether coupled with the tethered anchors to reduce a diameter of the valve annulus.

51. (original) A device as in claim 46, further comprising at least a second stabilizing member movably coupled with the elongate shaft, wherein the second stabilizing member may be moved toward the first stabilizing member to further stabilize the valve annulus.

52. (original) A device as in claim 51, further comprising at least one anchor receiving piece coupled with the second stabilizing member for receiving distal ends of the plurality of anchors driven through the tissue of the valve annulus.

53. (original) A device as in claim 35, wherein the first stabilizing member comprises at least one deployable mechanical support structure for constricting the valve annulus.

54. (original) A device as in claim 53, wherein the mechanical support structure comprises at least one shape memory stent couplable with the valve annulus, wherein the stent longitudinally shrinks when deployed to constrict the valve annulus.

55. (original) A device as in claim 35, wherein the first stabilizing member comprises at least one energy delivery member for delivering energy to the valve annulus to constrict the annulus.

56. (original) A device as in claim 55, wherein the energy delivery member comprises a radiofrequency delivery member.

57. (original) A device as in claim 35, wherein the first stabilizing member comprises at least one drug delivery member for delivering at least one drug to the valve annulus to constrict the annulus.

58. (new) A method for constricting a heart valve annulus comprising:  
accessing a heart valve annulus from beneath one or more leaflets of a heart valve;

introducing a tethered clip assembly to the heart valve annulus, wherein the tethered clip assembly comprises a plurality of individual clips coupled to a tether;

securing the individual clips of the tethered clip assembly at circumferentially spaced apart locations about at least a portion of the heart valve annulus; and

cinching the tether to reduce the circumference of at least a portion of the heart valve annulus.

59. (new) The method of claim 58 wherein the heart valve annulus is a mitral valve annulus.

60. (new) The method of claim 58 performed on a beating heart.

**REMARKS**

Claims 1-60 remain in this case.

If the Examiner believes a telephone conference would aid the prosecution of this case in any way, please call the undersigned at (650) 712-0340.

Respectfully submitted,



---

James F. Hann, Reg. No. 29,719

Dated: 18 November 2004

HAYNES BEFFEL & WOLFELD LLP  
P.O. Box 366  
Half Moon Bay, California 94019  
Phone: 650-712-0340  
Fax: 650-712-0263  
JFH:pfh